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6 May 2019

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF LEVONORGESTREL INTRAUTERINE SYSTEM

PHARMAC invites proposals for the supply of the levonorgestrel intrauterine system in New Zealand.

This request for proposals (**RFP**) letter incorporates the following schedules:

- Schedule 1 specifies the pharmaceutical for which PHARMAC is requesting proposals and sets out the background to the RFP and the types of proposals sought;
- Schedule 2 describes the process that PHARMAC expects to follow in relation to the RFP;
- Schedule 3 sets out information about the estimated size of the current subsidised market for the pharmaceutical; and
- Schedule 4 contains the RFP form in which you are to provide details of your proposal.

If you wish to submit a proposal, you must submit it to PHARMAC via the Government Electronic Tenders Service (**GETS**) (www.gets.govt.nz) no later than 4.00p.m. on 30 May 2019.

If you have any questions about this RFP, please post these on GETS. Responses to all questions will be published on GETS.

We look forward to receiving your proposal.

Yours sincerely

Lisa Williams
Director of Operations

Schedule 1: Pharmaceutical, background to RFP and types of proposals sought

1. Pharmaceutical

PHARMAC is interested in considering proposals from suppliers for a levonorgestrel intrauterine system (**LIUS**).

For the avoidance of doubt, PHARMAC is not seeking proposals from suppliers of non-hormonal intrauterine devices (IUDs) or of hormonal long-acting reversible contraceptives in the form of an implant.

2. Background to RFP

LIUS is a hormone-releasing intrauterine device that consists of a T-shaped plastic frame that is inserted into the uterus and releases levonorgestrel. There are different strengths of LIUS available.

LIUS (52mg presentation, delivering 20mcg per day) (**52mg LIUS**) is indicated for:

- treatment of idiopathic menorrhagia (heavy menstrual bleeding);
- prevention of endometrial hyperplasia during oestrogen replacement therapy; and
- contraception.

LIUS (13.5mg and 19.5mg presentations, delivering average 6mcg per day and 17.5mcg per day, respectively) (respectively, **13.5mg LIUS** and **19.5mg LIUS**) are indicated for contraception.

LIUS are generally registered for use for a period of three or five years, after which they need to be replaced.

History of Funding

On 1 October 2002, a 52mg LIUS (under the brand name Mirena) was listed subject to Special Authority criteria in Section B of the Pharmaceutical Schedule for use in the community for the indication of heavy menstrual bleeding.

On 1 July 2013, a 52mg LIUS (under the brand name Mirena) was listed subject to restrictions in Part II of Section H of the Pharmaceutical Schedule for use in District Health Board (DHB) Hospitals for the indication of heavy menstrual bleeding.

On 1 December 2013, PHARMAC widened the restrictions in Part II of Section H for the 52mg LIUS to include the treatment of the unregistered indication of endometriosis.

In September 2015, PHARMAC issued a request for proposals for the funding of LIUS. As a result of the request for proposals, PHARMAC awarded sole supply to Bayer (NZ) Ltd for its Mirena brand of 52mg LIUS. The agreement for sole supply with Bayer (NZ) Ltd ends on 30 June 2019.

Current Funding

(a) PHARMAC currently lists the 52mg LIUS (Mirena brand) in Section B of the Pharmaceutical Schedule for use in the community subject to the following Special Authority criteria:

Initial application – (no previous use) only from a relevant specialist or general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

1 The patient has a clinical diagnosis of heavy menstrual bleeding; and
2 The patient has failed to respond to or is unable to tolerate other appropriate pharmaceutical therapies as per the Heavy Menstrual Bleeding Guidelines; and
3 Either:
    3.1 serum ferritin level < 16 mcg/l (within the last 12 months); or
    3.2 haemoglobin level < 120 g/l.

Note: Applications are not to be made for use in patients as contraception except where they meet the above criteria.

Renewal only from a relevant specialist or general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

1 Either:
    1.1 Patient demonstrated clinical improvement of heavy menstrual bleeding; or
    1.2 Previous insertion was removed or expelled within 3 months of insertion; and
2 Applicant to state the date of previous insertion.

(b) PHARMAC currently lists the 52mg LIUS (Mirena brand) in Part II of Section H of the Pharmaceutical Schedule (for DHB Hospital use) subject to the following restrictions:

Initiation – heavy menstrual bleeding

Obstetrician or gynaecologist

All of the following:

1 The patient has a clinical diagnosis of heavy menstrual bleeding; and
2 The patient has failed to respond to or is unable to tolerate other appropriate pharmaceutical therapies as per the Heavy Menstrual Bleeding Guidelines; and
3 Any of the following:
    3.1 Serum ferritin level < 16mcg/l (within the last 12 months); or
    3.2 Haemoglobin level < 120g/l; or
    3.3 The patient has had a uterine ultrasound and either a hysteroscopy or endometrial biopsy.

Continuation – heavy menstrual bleeding

Obstetrician or gynaecologist

Either:

1 Patient demonstrated clinical improvement of heavy menstrual bleeding; or
2 Previous insertion was removed or expelled within 3 months of insertion.

Initiation – endometriosis

Obstetrician or gynaecologist

The patient has a clinical diagnosis of endometriosis confirmed by laparoscopy.

Continuation – endometriosis

Obstetrician or gynaecologist

Either:

1 Patient demonstrated satisfactory management of endometriosis; or
2 Previous insertion was removed or expelled within 3 months of insertion.

Note: endometriosis is an unregistered indication.

Reason for running the RFP

The purpose of this RFP is to:

(a) secure competitive pricing for the supply of LIUS;

(b) secure supply of LIUS for three years, possibly extending for two additional periods of one year each; and

(c) determine if widened funded access to LIUS would be possible.

Relevant clinical advice

PHARMAC has obtained clinical advice from the Pharmacology and Therapeutics Advisory Committee (**PTAC**) and the Reproductive and Sexual Health (**RASH**) Subcommittee of PTAC. The minutes can be found on the PHARMAC website as linked below:

- April 2017 RASH Subcommittee meeting; and
- February 2018 PTAC meeting.

April 2017: RASH recommended that LIUS for contraception be listed on the Pharmaceutical Schedule with a high priority.

April 2017: RASH recommended that community funded access be widened to LIUS with a high priority, for women with heavy menstrual bleeding, endometrial hyperplasia without atypia, and endometriosis.

February 2018: PTAC recommended:

- that LIUS for the treatment of endometriosis be listed with a high priority in Section B and Part ll of Section H of the Pharmaceutical Schedule;
- that LIUS for the treatment of endometrial hyperplasia without atypia be listed with a high priority in Section B and Part ll of Section H of the Pharmaceutical Schedule;
- that widened access of LIUS for the treatment of heavy menstrual bleeding be listed with a high priority in Section B and Part ll of Section H of the Pharmaceutical Schedule; and
- that LIUS for contraception be listed with a high priority in Section B and Part ll of Section H of the Pharmaceutical Schedule.

PTAC and RASH also considered that it would be appropriate to fund either a three-year or a five-year LIUS for any or all of these indications, taking into account the indicated uses of unfunded presentations.

Table 1. Current LIUS funded access and options for widened access

	Community	**Hospital**
Current Access:	<u>Heavy menstrual bleeding</u> • A clinical diagnosis of heavy menstrual bleeding; and • The patient has failed to respond to or is unable to tolerate other appropriate pharmaceutical therapies as per the Heavy Menstrual Bleeding Guidelines; and • Requirement for secondary anaemia	<u>Heavy menstrual bleeding</u> • A clinical diagnosis of heavy menstrual bleeding; and • The patient has failed to respond to or is unable to tolerate other appropriate pharmaceutical therapies as per the Heavy Menstrual Bleeding Guidelines; and • Requirement for secondary anaemia or patient has had a uterine ultrasound and either a hysteroscopy or endometrial biopsy
		<u>Endometriosis</u> • The patient has a clinical diagnosis of endometriosis confirmed by laparoscopy
Widened Access Options:	<u>Heavy menstrual bleeding</u> • A clinical diagnosis of heavy menstrual bleeding; and • The patient has failed to respond to or is unable to tolerate other appropriate pharmaceutical therapies as per the Heavy Menstrual Bleeding Guidelines	<u>Heavy menstrual bleeding</u> • A clinical diagnosis of heavy menstrual bleeding; and • The patient has failed to respond to or is unable to tolerate other appropriate pharmaceutical therapies as per the Heavy Menstrual Bleeding Guidelines
	<u>Endometrial hyperplasia without atypia</u> • A clinical diagnosis of endometrial hyperplasia without atypia	<u>Endometrial hyperplasia without atypia</u> • A clinical diagnosis of endometrial hyperplasia without atypia
	<u>Endometriosis*</u> • A clinical diagnosis of endometriosis	<u>Endometriosis*</u> • A clinical diagnosis of endometriosis
	<u>Contraception</u>	<u>Contraception</u>

*note that the “endometriosis’ indication would include the “endometrial hyperplasia without atypia” indication.

Any proposals progressed for consideration for funding would be assessed using PHARMAC’s decision-making framework as outlined in its Operating Policies and Procedures (**OPPs**) with reference to the Factors for Consideration.

3. **Types of proposals sought**

Suppliers of the 52mg LIUS **MUST** submit proposals:

(a) for supply of the 52mg LIUS for the currently funded indications, as set out in the above table, (for the avoidance of doubt, for the currently funded indications, PHARMAC will only consider the 52mg LIUS); and

(b) that include a period of sole subsidised supply in the community and hospital supply status in DHB Hospitals ("**Sole Supply**") for a period of up to three years, with the possibility of extending to two additional periods of one year each.

Suppliers of the 52mg LIUS **MAY** submit proposals:

(c) for the Sole Supply of LIUS for widened funded access, as set out in the above table, beyond the currently funded indications, provided that the supplier also submits a separate proposal solely for the supply of the currently funded indications as per (a) and (b) above. A decision to widen funding access may be subject to further clinical advice and analysis and is dependent on budget availability. PHARMAC is willing to consider proposals for all or a selection of the widened access options for LIUS below (collectively, "**Widened Access Options**") for:

(i) menstrual bleeding (removal of requirement for secondary anaemia);

(ii) endometrial hyperplasia without atypia or endometriosis (noting that the latter would include the former)[1]; or

(iii) contraception.

(d) that include bundling for Sole Supply of LIUS for the currently funded indications and Widened Access Options, provided that individual proposals are also submitted for both the current funded indications and any Widened Access Options, each capable of being accepted on its own.

Suppliers of the 13.5mg LIUS and 19.5mg LIUS **MAY** submit proposals:

(e) for the Sole Supply of LIUS for the Widened Access Option of contraception.

Suppliers of the 52mg LIUS that also supply either or both of the 13.5mg LIUS and 19.5mg LIUS **MAY** submit proposals:

(f) that include the bundling of Sole Supply of the 52mg LIUS with either or both of the 13.5mg LIUS and the 19.5mg LIUS, provided that the individual proposals are also submitted for each presentation, each capable of being accepted on its own. For the avoidance of doubt, the 52mg LIUS will be considered for all currently funded indications and all Widened Access Options, while the 13.5mg LIUS and 19.5mg LIUS will only be considered for the Widened Access Option of contraception.

[1] PHARMAC is willing to consider proposals that include the indication of endometrial hyperplasia without atypia or endometriosis. While these are not approved indications for LIUS, section 25 of the Medicines Act 1981 permits an authorised prescriber to use any medicine (approved or unapproved) for the treatment of a particular patient.

PHARMAC is also willing to consider the following types of proposals:

(a) proposals that include a period of subsidy protection in the community and price protection in DHB Hospitals and/or protection from delisting;

(b) proposals that include rebates or other risk-sharing arrangements; and

(c) proposals that include pharmaceuticals that have not yet gained all necessary Consents. "Consents" means all consents, permits, licences and authorisations, whether statutory or otherwise, required for the supply of the pharmaceutical in New Zealand (including Ministry of Health market approval). In these circumstances, suppliers may be required to demonstrate their ability to obtain those consents within a time frame acceptable to PHARMAC.

In addition, please note:

(a) Proposals that would require a brand change for the currently funded indications must include a six-month transition period between listing the new brand of LIUS and commencement of any Sole Supply arrangement.

(b) Any supplier awarded Sole Supply would be expected to cover the cost of any replacement for LIUS expelled within three months of insertion.

(c) Any supplier awarded Sole Supply would be expected to implement training of clinicians nationwide in the use (including insertion and removal) of its product. An outline of the supplier's proposed training program and timetable for regional coverage and delivery must be supplied with the proposal.

(d) Suppliers should provide PHARMAC with samples of the LIUS presentations included in their proposal (and, if supply is intended to be in a different presentation, form and strength from the provided samples, information about differences must be supplied) within 10 business days from the dated specified in Schedule 2, clause 1(b).

PHARMAC is **NOT** willing to consider the following types of proposals:

(a) proposals that include pharmaceuticals other than levonorgestrel IUS;

(b) hormonal long-acting reversible contraceptives in the presentation of a non-IUS contraceptive implant;

(c) a non-hormonal intrauterine device (IUD);

(d) proposals that involve listing a LIUS with a partial subsidy;

(e) cross-deal or bundling arrangements in respect of more than one chemical entity, therapeutic group or sub-group;

(f) proposals that involve expenditure caps;

(g) proposals that involve an end date for a rebate or other risk-sharing arrangement;

(h) two-part pricing arrangements, whereby PHARMAC may make an up-front payment (in addition to any ongoing subsidy) in return for the listing of a pharmaceutical on specific terms;

(i) parity pricing, whereby PHARMAC may reduce the subsidy payable for a pharmaceutical in a particular therapeutic sub-group to the level of the subsidy payable for a pharmaceutical in any other sub-group; and

(j) proposals that involve foreign currency exchange rate clauses or prices linked to any index.

Subject to the above, PHARMAC is open to considering any other types of proposals you may wish to put forward.

Schedule 2: RFP process

PHARMAC expects to follow the process set out below in the sequence indicated.

1. Submission

(a) You may submit more than one proposal. Each proposal will be considered as a separate proposal.

(b) Proposals must be submitted to PHARMAC via the Government Electronic Tenders Service (GETS) no later than **4:00pm** (New Zealand time) on 30 May 2019. Late proposals will only be considered at PHARMAC's discretion, considering the need for fairness to other suppliers and integrity of the RFP process.

(c) You cannot withdraw your proposal, once submitted, while the RFP process is continuing.

(d) If you have any questions about this RFP, you should submit them on GETS. Responses to questions will be published on GETS.

2. Evaluation

(a) Following the deadline for submitting proposals an Evaluation Committee comprising PHARMAC staff will evaluate each proposal to select its preferred proposal(s).

(b) The Evaluation Committee will evaluate proposals in light of PHARMAC's statutory objective which is "to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided". In doing so the Evaluation Committee will be guided by the Factors for Consideration (**Factors**) that form part of PHARMAC's then current OPPs, as published on PHARMAC's website (www.pharmac.govt.nz), to the extent applicable. More information on the Factors can be found at www.pharmac.health.nz/factors-for-consideration.

(c) The requirement for PHARMAC to pursue its statutory objective means that particular emphasis will be given to those aspects of proposals which demonstrate "health outcomes", and those aspects of proposals which demonstrate the impact on the "funding provided" for pharmaceuticals. Those Factors which relate directly to these aspects will be given the greatest weight by the Evaluation Committee but all Factors are important.

(d) The information to be taken into account in applying the Factors by the Evaluation Committee will be at its discretion, however it will include:

(i) information provided by you in accordance with Schedule 4 of this RFP;

(ii) lead times;

(iii) any advice from PTAC or its relevant Subcommittee, any advice from PTAC, its relevant subcommittee, any relevant professional organisation or healthcare professionals. This may include specific clinical advice regarding relative risks and benefits of LIUS following the closing of this RFP; and

(iv) detailed national education and training plan; and

(v) any other information that the Evaluation Committee considers to be relevant, having regard to probity principles.

(e) Each proposal will be evaluated on the basis that the price offered, the expenditure entailed, and any other terms included in the proposal, are the best that the supplier is able to offer. If you do not put forward your best terms you risk having your proposal excluded at the evaluation stage.

(f) PHARMAC is not bound to select the lowest priced proposal or any proposal.

3. PHARMAC may request further information

(a) PHARMAC may request such further information as it considers necessary from or about you for the purposes of clarifying or evaluating your proposal, including (but not limited to):

(i) detailed information about your company structure, credit status and any other relevant company information; and

(ii) any other additional information about your pharmaceutical.

Please note that PHARMAC may seek advice from PTAC, its relevant subcommittee, any relevant professional organisations or healthcare professionals with regard to your product, including evaluation of any product samples.

(b) If PHARMAC requests further information from or about you, it is not obliged to request the same or any other information from or about any other party, provided that in PHARMAC's judgment this would not be unfair to any other party.

4. Negotiation

(a) PHARMAC may negotiate with the submitter(s) of one or more preferred proposals, in the latter case whether or not the acceptance of either supplier's proposal would exclude acceptance of the other proposal.

(b) Negotiations will proceed on the basis that PHARMAC's standard terms and conditions for supply of pharmaceuticals, which are available on request from PHARMAC, will apply.

(c) Given that PHARMAC expects your proposal to be the best you can offer, PHARMAC does not intend to initiate negotiation with you on price. However, PHARMAC does not exclude the possibility that the final price agreed will be different from the price put forward in your proposal, as a result of the impact that other negotiated terms may have on price.

(d) PHARMAC may negotiate and enter into a provisional agreement with a preferred supplier(s) on whatever special terms, in addition to PHARMAC's standard terms and conditions, PHARMAC considers appropriate.

(e) If PHARMAC and the supplier(s) are unable to reach a provisional agreement within what PHARMAC considers to be a reasonable time, PHARMAC may terminate those negotiations and negotiate with a different supplier(s).

5. Consultation and approval

(a) Any provisional agreement will be conditional on consultation with suppliers and other interested parties, to the extent PHARMAC considers consultation to be necessary or appropriate, and on, Board approval (or approval by the Board's delegate acting under delegated authority).

(b) PHARMAC will not consider any counter-offers received during consultation.

(c) The provisional agreement and responses to consultation will be considered by PHARMAC's Board (or by the Board's delegate acting under delegated authority) in accordance with the decision criteria in PHARMAC's then current OPPs.

(d) If the Board or its delegate does not approve the provisional agreement, then PHARMAC may initiate negotiations for a provisional agreement with any other supplier(s).

(e) The RFP process will be complete once PHARMAC has notified suppliers of either:

(i) the Board's or its delegate's decision to accept a negotiated agreement; or

(ii) the termination of the RFP process.

6. Miscellaneous

(a) PHARMAC reserves the right, having regard to probity principles:

(i) to make such adjustments to the above RFP process as it considers appropriate, at any time during the process, provided that it notifies suppliers affected by those changes;

(ii) not to accept any proposal;

(iii) to seek clarification of any proposal;

(iv) to meet with any supplier in relation to its proposal(s);

(v) to enter into an agreement or arrangement that differs in material respects from that envisaged in this RFP letter;

(vi) to suspend this RFP process. For example, if during the RFP process (and before a provisional agreement is entered into) it becomes apparent to PHARMAC that further consultation is appropriate or required we may suspend the RFP process in order to consult. In this situation we may ask you to adapt and resubmit your proposal in light of consultation, or alternatively we may request that new proposals be submitted;

(vii) to terminate this RFP process at any time, by notifying suppliers who submitted proposals, and, following termination, to negotiate with any supplier(s) on whatever terms PHARMAC thinks fit;

(viii) to re-advertise for proposals.

(b) PHARMAC may consult or seek clinical advice from PTAC or its relevant sub-committee at any stage of the RFP process. PHARMAC will notify you if the clinical advice results in any changes to the terms of the RFP.

(c) You must not initiate or engage in any communication with other suppliers in relation to the RFP, whether before or after submitting your proposal(s), until such time as a provisional agreement is accepted by PHARMAC's Board or the Board's delegate.

(d) You must not at any time initiate any communication with PHARMAC, the Ministry of Health (including its operating unit Medsafe), the Minister of Health (or any Associate Ministers) or DHBs, or advisors to PHARMAC with a view to influencing the outcome of this RFP process.

(e) You must pay your own costs for preparing and submitting your proposal(s).

(f) Proposals are submitted in reliance on your own knowledge, skill, and independent advice, and not in reliance on any representations made by PHARMAC.

(g) Your submission of a proposal will be taken as acceptance of the terms contained in this RFP letter. PHARMAC may exclude your proposal if you do not comply with any of the terms contained in this RFP letter.

(h) This is an RFP and not a tender. Your proposal is not an offer capable of being converted into a contract for the supply of LIUS by PHARMAC's apparent acceptance and instead a separate agreement needs to be negotiated.

(i) PHARMAC is not liable in any way whatsoever for any direct or indirect loss (including loss of profit), damage or cost of any kind incurred by you or any other person in relation to this RFP.

(j) PHARMAC will consider your proposal and information exchanged between us in any negotiations relating to your proposal, excluding information already in the public domain, to be confidential to us and our employees, legal advisors and other consultants, the Ministry of Health and DHBs (**Confidential Information**). However, you acknowledge that it may be necessary or appropriate for PHARMAC to release Confidential Information:

(i) pursuant to the Official Information Act 1982; or

(ii) in the course of consultation on a provisional agreement entered into with a supplier; or

(iii) in publicly notifying any approval by the PHARMAC Board (or its delegate) of that agreement; or

(iv) otherwise pursuant to PHARMAC's public law or any other legal obligations.

PHARMAC may consult with you before deciding whether to disclose Confidential Information for the purposes described in sub-clauses (i) to (iv) above. You acknowledge, however, that it is for PHARMAC to decide, in its absolute discretion, whether it is necessary or appropriate to disclose Confidential Information for any of the above purposes, provided that PHARMAC shall act in good faith in disclosing any Confidential Information.

7. Anticipated timetable

(a) Following receipt of proposals, PHARMAC anticipates:

(i) the Evaluation Committee evaluating proposals in June 2019;

(ii) seeking clinical advice (if necessary) in June/July 2019;

(iii) negotiating with submitter(s) of one or more preferred proposals in July/August 2019;

(iv) consulting on a provisional agreement in September 2019;

(v) PHARMAC's Board, or the Board's delegate, considering this provisional agreement in or after October 2019;

provided that the above time frames are only approximate and may be extended, without notice being required from PHARMAC, if any stages of the RFP process take longer than anticipated.

(b) Under this indicative timetable, PHARMAC expects the earliest that changes to the Pharmaceutical Schedule could be implemented is 1 November 2019.

(c) Please note that if a proposal for Sole Supply is accepted, the date of implementation may be later to allow for an orderly transition to any Sole Supply arrangement.

8. Governing Law

This RFP is governed by New Zealand law, and the New Zealand courts have exclusive jurisdiction in all matters relating to this RFP.

Schedule 3: Current listing and market information

The following information relates to the estimated subsidised market size of LIUS under the current eligibility criteria and restrictions. The information is approximate and indicative only. PHARMAC makes no representation as to the accuracy of this information or as to the level of sales or likely sales of LIUS and, while PHARMAC has taken all reasonable care in preparing the information set out below, it accepts no liability for any errors or omissions in the information. PHARMAC is not obliged to notify you in the event of any change to the figures below.

Table 2. Usage of 52 mg LIUS (units) in the last three financial years

	FYE 30 June 2016	**FYE 30 June 2017**	**FYE 30 June 2018**
Community	4,915	5,192	5,388
Hospital	4,255	4,952	4,993

Table 3. Estimates of LIUS usage (units) for Widened Access Options

Indication	**Estimated units per year**
Endometrial hyperplasia without atypia	500 units
Endometriosis (includes the numbers for endometrial hyperplasia without atypia above)	1300 units
Heavy menstrual bleeding (removing requirement for secondary anaemia)	5,000 units
Contraception	16,500 units

Schedule 4: Proposal form

An electronic version of this form is available on GETS (www.gets.govt.nz). You should expand the boxes as necessary.

[***Supplier to insert date***]

Director of Operations
PHARMAC
C/- Jeremy Price

By electronic transfer using GETS **(www.gets.govt.nz)**

Dear Sir/Madam

Proposal for the supply of levonorgestrel intrauterine system

In response to your request for proposals (**RFP**) dated 6 May 2019, we put forward the following proposal in respect of levonorgestrel intrauterine system.

Set out below is further information in support of our proposal.

(a) Our contact details:

Name of supplier	
Contact person	
Address	
Phone	
Facsimile	
Email address	

(b) Details of pharmaceutical presentation:

Chemical name	
Strength (e.g. 52mg, 19.5mg, 13.5mg)	
Form(s) (e.g. injection)	
Brand name	
Pack size (e.g. 6 injections)	
Packaging type (e.g. prefilled syringe)	

(c) Details of pharmaceutical manufacture:

Name and address of manufacturer/s of the pharmaceutical (including	

API manufacturer, manufacturer of final dose form, packaging etc)	
Lead time (Time from notification of award to product being available to supply the New Zealand market)	
Details on pharmaceutical manufacturing sites and their registration with Medsafe or other international regulatory body (e.g. TGA, FDA, MHRA)	
Batch size/s	
Approximate manufacture time	
Approximate time for shipping	

(d) Key features of our proposal:

(e) Information relating to pricing ($NZ, GST exclusive), including any related conditions or proposed terms affecting cost for PHARMAC:

(f) Evidence of market approval and any other required consents:

Date of market approval (please attach copy of Medsafe Gazette notice)	
OR Date of submission of dossier or changed-medicine notification submission (please attach confirmation from Medsafe that this has been submitted)	
OR Expected date of dossier or changed-medicine notification submission to Medsafe (please provide details)	

(g) Confirmation that there are no intellectual property barriers (including patent barriers) to our supply of this product in New Zealand, with additional information if required:

(h) Information about our ability to ensure the continuity of supply of the pharmaceutical, including other countries where the product is provided:

(i) Information about our previous supply performance, existing supply commitments and relevant expertise:

(j) Proposals/suggestions (e.g. pricing, risk sharing arrangements, etc) regarding the pharmaceutical not expressly identified in this RFP that we would like PHARMAC to consider as part of our proposal:

(k) Reasons why PHARMAC should accept our proposal:

(l) Details of nationwide training plan we would deliver if successful:

(l) Additional information that PHARMAC should consider when evaluating our proposal (e.g. if applicable, an estimate of any savings to the patient and/or health system as a result of less-frequent injections). Please include information you consider relevant under PHARMAC's Factors for Consideration decision making framework: